

U.S. Patent Application Serial No. **10/566,085**
Response filed February 25, 2010
Reply to OA dated November 2, 2009

REMARKS

Claims 3, 4, 6-8, 15 and 18 are pending in this application. Claims 7, 8, 15 and 18 are canceled without prejudice or disclaimer, and claims 3, 4 and 6 are amended herein. Upon entry of this amendment, claims 3, 4 and 6 will be pending. Entry of this amendment and reconsideration of the rejections are respectfully requested.

No new matter has been introduced by this Amendment. Support for the amendments to the claims is discussed below.

Claims 3-6 [sic] are rejected under 35 U.S.C. 101 because the claims read on the organism per se which is found in nature and thus, is unpatentable to applicant. (Office action page 3)

The rejections of claims 3, 4 and 6 are respectfully traversed. Applicant notes that claim 5 is not pending in the application.

In traversing the rejection, Applicant argues, first of all, that the *Lactobacillus casei* strain FERM BP-10059 claimed in Claim 3 is **artificially manufactured** through the process of acclimatization of the original *Lactobacillus casei*, which is a known strain. The process of manufacturing the present strain is described in detail in the specification on page 17, line 10, to page 24, line 5.

Table 1 of the specification compares various properties of the *Lactobacillus casei* strain of the present invention with the conventional strain. As can be seen in Table 1, the *Lactobacillus casei*

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strain of the present invention differs from the conventional strain in almost every property listed. This demonstrates that the *Lactobacillus casei* strain of the present invention is completely different in property from the conventional one.

That is, the strain claimed in Claim 3 is not found in nature, and is a **new strain manufactured** by the present inventors.

The Examiner states that the claims read on “an organism per se which is found in nature” and recommends reciting “a biologically pure culture” Claim 3 has been amended to recite “A biologically pure culture,” as suggested by the Examiner.

In addition to the above arguments regarding base claim 3, claim 4 requires “a preservative” and claim 6 requires “an antibiotic.” These additional components further distinguish these claimed compositions from any compositions found in nature.

Claims 4, 6-8, 15 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. (Office action page 3)

The rejection is moot for claims 7, 8, 15 and 18, which are canceled without prejudice or disclaimer. The rejection of claims 4 and 6 is overcome by the amendments to these claims.

The Examiner states that the “amount of strain *Lactobacillus casei* FERM BP-10059 in the various compositions and methods is not set forth in the claims with any particularity. The concentrations intended for the strain and the antibiotic or disinfectant cannot be readily assessed

in the context of the claimed invention. Similarly, there is no clear indication whether the compositions contain live or dead bacteria.”

With regard to “the concentrations intended for the strain and the antibiotic or disinfectant,” Applicant submits that it is completely conventional to recite compositions as comprising chemical components without specifying the concentration of those components.

With regard to the comment regarding “dead” or “live” bacteria, claims 4 and 6 have been clarified to read: “purified bacterial cells or freeze-dried cells of the biologically pure culture of the *Lactobacillus casei* strain”

Support for this amendment may be found in the “freeze-dried bacterial cells” described in Manufacturing Examples 1 and 2 and the “wet bacterial cells” described in Manufacturing Example 2. This amendment is also supported by Manufacturing Example 4.

The Examiner also states that the term “preservative” in claim 4 is unclear. This is a preservative for the freeze-dried bacterial cells, that is, a compound that keeps the freeze-dried preparation viable. The technology of manufacturing freeze-dried bacterial cells is well known in the art of microorganisms, and the term “preservative” as used in the claim is well understood to any person having ordinary skill in the art.

For example, Manufacturing Example 1 of the present description discloses that the purified bacterial mass was placed in a solution consisting of skim milk, soluble starch, sodium glutamate and purified water, and vacuum freeze dried for removing water to obtain the bacterial preparation. It is clear to one having ordinary skill in the art that the preservatives in this preparation are skim

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milk, soluble starch and sodium glutamate. Likewise, in Manufacturing Example 2, skim milk, soluble starch trehalose and cysteine are the preservatives.

Support for the amendment to claim 6 may also be found in Manufacturing Examples 4 and 5, Examples 20, 21, 23, 24, 25 and 26, etc., in the specification.

Regarding claim 6, the Examiner states that the recitation of “preventative or therapeutic agent” in the preamble is confusing and vague, because the composition includes an antibiotic and because it is unclear what is intended to be prevented. However, Applicant respectfully notes that the preamble reads “preventative or therapeutic agent **against infections** in humans, animals and plants.” That is, the preamble does state what is to be prevented or treated by the composition, and this is well supported by the specification, such as the treatment of various diseases including periodontal disease (see Table 27), chronic sinusitis, chronic bronchitis and bed sores (see Table 31).

Moreover, the Examiner’s comment regarding the “unknown amounts” of antibiotic in claim 6 does not provide a proper basis for a rejection under 35 U.S.C. 112, second paragraph. As noted above, it is conventional to recite compositions comprising various components without specific limitations on their amounts, and there is no requirement under 35 U.S.C. 112, second paragraph, that concentrations be recited.

Claims 4, 6-8, 15 and 18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

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enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. (Office action page 4)

The Examiner states that it is not clear if the deposit meets all of the criteria of 37 CFR 1.801-1.809. The Examiner states on page 5 that “it may be averred that deposited material has been accepted for deposit under the Budapest Treaty ...” The Examiner states that Applicant’s previous response was missing the statement averring that all restrictions on the availability of the material deposited will be irrevocably removed upon the granting of a patent.

Applicant hereby corrects this oversight by making the requested statement, which is clearly made under the following heading:

STATEMENT IN ACCORDANCE WITH 37 CFR 1.808 AND MPEP 2410.01

In accordance with 37 CFR 1.808, Applicant hereby affirms that the deposit of FERM BP-10059 was made under the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon granting of a patent for the present application.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Matrozza (US Patent no. 4,579,740). (Office action page 6)

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Applicant respectfully notes that Matrozza appears to be a newly cited reference, and has not yet been made of record in an IDS or a form PTO-892. Applicant respectfully requests the Examiner to cite this reference in a form PTO-892.

The Examiner cites Matrozza for disclosing a composition comprising a strain of *L. casei* and a preservative. The Examiner states that “**even though the strains are not necessarily the same**, the amount as claim designated does not patentably distinguish the invention” (emphasis added).

The rejection is respectfully traversed, and reconsideration is requested.

First of all, Matrozza discloses *L. casei* strain NRRL-B-15,438. The Examiner has given **no rationale** for assuming that *L. casei* strain NRRL-B-15,438 is the same as FERM BP-10059. In fact, the Examiner appears to acknowledge that the strain in Matrozza is not the same as the presently claimed strain.

If Matrozza’s *L. casei* strain NRRL-B-15,438 is not the same as FERM BP-10059, there can be no issue of anticipation of the present claim. Moreover, since the reference **does not suggest using any other *L. casei* strain**, if NRRL-B-15,438 is not the same as FERM BP-10059, there can be no *prima facie* case of obviousness. There is absolutely no motivation in the reference to substitute any other *L. casei* strain, in particular, one that is unknown in the art, and there is no motivation to modify Matrozza’s strain to produce a new strain.

In this regard, Applicant notes that the strain claimed in present base claim 3 has a variety of characteristics, as shown in Table 1, clearly distinguishing itself from Matrozza's strain. Specifically, it has distinguishable effects on the following points:

(1) Since the strain claimed in claim 3 has antibiotic productivity, it can subdue the proliferation of another bacteria with no use of antibiotic;

(2) Since the strain is amylolytic, it can use starches abundantly present throughout the natural world as energy sources, and therefore it can colonize, survive and proliferate in living bodies. Fortunately, most bacteria that cause chronic infections are incapable of obtaining energy from the breakdown of starch, so giving the *Lactobacillus casei* species this ability is particularly effective as a measure against infections (see English specification page 21, line 5 from the bottom, to page 22, line 3 from the bottom).

(3) The *Lactobacillus* promotes the growth and proliferation of *chlorella*. This means that the substances produced by this *lactobacillus* activate and having a restorative effect on living cells (see English specification page 22, line 2 from the bottom, to page 24, line 5).

As mentioned above, the preparation containing the *Lactobacillus casei* strain of the present invention shows functions and effects which are characteristic of this particular *Lactobacillus casei* strain. Accordingly, the preparation of the present invention shows functions and effects which are remarkably different from the preparation containing the ordinary *Lactobacillus casei* strain.

2) As for the *Lactobacillus casei* NRRL-B-15,438 disclosed in Matrozza, Matrozza is silent about antibiotic productivity or growth and proliferation of chlorella, and it is described that "starch

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is not fermented by the culture" (abstract). Therefore, Matrozza's strain is considered to have a similar nature to that of the conventional *Lactobacillus*.

Nor does Matrozza disclose or suggest that the *Lactobacillus casei* be acclimatized to strengthen the antibiotic productivity to give amylolytic ability, or ability to promote the growth and proliferation of chlorella. Therefore, there is no motivation to one having ordinary skill in the art, by reading Matrozza, to acclimatize the *Lactobacillus casei* NRRL-B-15,438 to manufacture another *Lactobacillus casei* strain, such as that in the present invention.

To summarize, Matrozza's *L. casei* strain NRRL-B-15,438 is not the same as the strain of base claim 3. Moreover, neither Matrozza nor any of the references of record discloses or suggests acclimatization of the *Lactobacillus* strain to strengthen the antibiotic productivity, to give amylolytic ability or to give ability to promote the growth and proliferation of *chlorella*. There is no suggestion or motivation in the art to produce the presently claimed *L casei* strain.

Claims 4-5 [sic] are rejected under 35 U.S.C. 103(a) as being unpatentable over Hata et al (U.S. Patent No. 4,314,995). (Office action page 6)

Applicant respectfully notes that claim 5 is not pending in the application. The rejection of claim 4 is respectfully traversed.

The Examiner cites Hata for disclosing a strain of *L. casei* and an antibiotic. The Examiner states that: "Even though the strains are not necessarily the same, the composition as claimed does

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not patentably distinguish the invention. An antibiotic is deemed to act as a preservative at least to some extent.”

In traversing the rejection, Applicant submits, as in the above rejection over Matrozza, that if the strain of *L. casei* in Hata is different from FERM BP-10059, there can be no *prima facie* case of obviousness. The Examiner has not given any argument that these strains would inherently be the same, or that there is a suggestion in Hata for FERM BP-10059. Moreover, Applicant submits that Hata’s strain is clearly different from that in the present claims, and Applicant’s above arguments regarding Matrozza are applicable to Hata; that is, there is no motivation in the art to modify Hata’s strain so as to produce the strain of the present invention.

Moreover, as noted above, a “preservative” in claim 4 is a substance that keeps the bacteria viable. Hata’s antibiotic cannot be a “preservative” as in claim 4.

Claims 4-5 [sic] are rejected under 35 U.S.C. 103(a) as being unpatentable over Asahara et al. (Antimicrobial Agents and Chemotherapy, June 2001, Vol. 45, p. 1751-1760) taken with Ouwehand et al. (Journal of Food Science, Vol. 66, No. 6, pages 856-858, 2001). (Office action page 6)

Applicant respectfully notes that claim 5 is not pending in the application. The rejection of claim 4 is respectfully traversed.

Asahara is cited for disclosing a strain of *L. casei* and an antibiotic. The Examiner states, as in the above rejections: “Even though the strains are not necessarily the same, the composition as

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claimed does not patentably distinguish the invention. An antibiotic is deemed to act as a preservative at least to some extent.”

Therefore, the issues in this rejection are the same as those in the rejections over Matrozza and Hata et al. Applicant submits, as above, that there is no suggestion in the cited art for the claimed strain FERM BP-10059.

In particular, Asahara discloses the antimicrobial activity of the intraurethrally administered probiotic *Lactobacillus casei* strain *Shirota* in a murine urinary tract infection model. This strain is not acclimatized, and therefore is considered to be a conventional strain.

Ouwehand teaches that *Lactobacillus casei Shirota* showed a low percentage of binding to intestinal mucus (see Fig. 1 and Table I). This strain is not acclimatized, either, and therefore is considered to be a conventional strain.

That is, the strains in the cited references are clearly different from the strain FERM BP-10059 in the present claims, and as argued above, there is no suggestion or motivation in the references for modifying the disclosed strains in any way that could possibly produce strain FERM BP-10059.

Reconsideration of the rejections is respectfully requested.

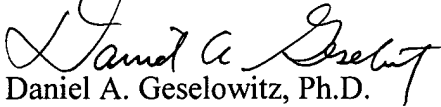
If, for any reason, it is felt that this application is not now in condition for allowance, the Examiner is requested to contact the applicants' undersigned agent at the telephone number indicated below to arrange for an interview to expedite the disposition of this case.

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In the event that this paper is not timely filed, the applicants respectfully petition for an appropriate extension of time. Please charge any fees for such an extension of time and any other fees which may be due with respect to this paper, to Deposit Account No. 01-2340.

Respectfully submitted,

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Enclosure: Petition for Extension of Time

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